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08/102,390 08/05/93 SKOULTCHI

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A CELL 3.3
EXAMINER

ZISKAS

ART UNIT PAPER NUMBER

1804

6

1804

DATE MAILED:

03/14/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 8/5/93 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three⁽³⁾ month(s), zero⁽⁰⁾ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

- ☒ Claims 1,26-71 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☒ Claims 2-25 have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 1,26-71 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
- ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

Art Unit: 1804

ATTACHMENT TO FORM PTO-850

The Count

A cell line capable of expressing a gene product by a predetermined normally transcriptionally silent gene within the genome of said cell line, said genome having inserted therein a DNA regulatory segment operatively linked with said normally transcriptionally silent gene, said DNA regulatory segment being capable of promoting the expression of a gene product by said cell line.

This count is exactly the same word for word as claim 18 of the Chappel party, USPN 5,272,071, and thus, corresponds exactly to the count.

STATEMENTS UNDER 37 CFR 1.609(B)(2) and (3)

A. Claims of the application which correspond to the count.

Claims 105 and 106 of the application correspond to the count.

Claim 105 corresponds to the count because claim 105 claims activation of gene expression of a normally non-expressed target gene by inserting via homologous recombination a heterologous regulatory sequence in operable linkage to the non-expressed gene which allows the target gene product to be expressed by the host mammalian cell. Thus, if claim 105 were prior art with respect to the count, it would anticipate or render obvious the subject matter of the count.

Claim 106 corresponds to the count because claim 106 claims a particular cell, a particular heterologous regulatory sequence,

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and a specific target gene and is therefore a species of the above generic claim.

Note that the phrase "normally transcriptionally silent" is known in the art to also mean "normally non-expressed" and that applicant's claim language was amended to the term "normally non-expressed" in order to accurately track the language in the specification.

B. Claims in the patent which correspond to the count.

Claims 1, 2, 5, 9-12, 17, 18, 25, 26, 28 and 32-35 correspond to the count because the claims are directed to methods of making and using the product of claim 18 (the count). These claims are directed to methods of making and using a cell whose genome has been modified by homologous recombination. The homologous recombination event resulted in the insertion of a heterologous regulatory sequence in operable linkage to a predetermined, normally non-expressed endogenous target gene in the genome of the cell. No claim listed here contains limitations such as positive or negative selectable markers or amplifiable genes.

C. Claims in the patent which do not correspond to the count.

Claims 3, 4, 6-8, 13-16, 19-24, 27, 29-31 and 36-58 do not correspond to the count. These claims do not correspond because they claim further limitations such as the inclusion of amplifiable genes (claims 3, 8, 19-21, 27, 31, 40, 43-47, 53-55), positive selectable markers (4, 6, 13, 14, 29, 36, 37, 41, 48 and 49), negative selectable markers (7, 15, 16, 30, 38, 39, 42, 50 and 51) or modification of a target gene which IS normally expressed (22-24, 52, 56-58). Note that the specification at page 3, paragraph 2, "Summary of the Invention", lines 3-4, distinguishes between amplifiable genes and regulatory genes. The amplifiable gene, although a regulatory sequence in the sense that it regulates transcription and ultimately expression, is not included in the phrase "other regulatory sequences" and is considered to be distinct from regulatory sequences such as enhancers and promoters in the application specification as well

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as in the art. Further, the amplifiable genes are considered to be a type of positive selectable marker.

STATEMENT UNDER 37 CFR 1.609(B) (4)

Applicants are entitled to the benefit of the filing date of the earliest application, application serial no. 07/432,069, filed 11/06/89, since both applications have support for the same invention.